



**United Fresh Fruit &
Vegetable Association**

August 27, 2004

Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2004N-0230, Current Good Manufacturing Practices Regulations; Public Meetings;
69 FR 40312

Dear Sir or Madam:

Founded in 1904, the United Fresh Fruit and Vegetable Association (United) is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry; promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

We have a direct and vested interest in food safety, and as such, the Agency's efforts to revise the current good manufacturing practice (GMP) regulations. United applauds the Agency for considering such a revision and given the fact that the rule was last updated in 1986. Since that time, the entire food industry, including the produce industry, has undergone widespread change. The nation's food safety regulations must reflect those changes and adapt with the shifting food environment.

With this in mind, we believe that any revisions made to the GMPs must be science-based; easy to implement and manage; and cost effective. Overall, food safety must be the principle focus. Our industry's manufacturing partners across the nation build their food safety systems using the GMPs as their foundation. The Agency must ensure that this foundational basis is not lost during the revision process.

Producers of raw agricultural commodities, including fresh fruits and vegetables, are appropriately exempt from compliance with GMPs under Part 110 of Title 21 of the Code of Federal Regulations:

"The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more "raw agricultural commodities," as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public."

Yet, the Agency does not lack regulatory authority over fresh fruit and vegetable producers. Fresh fruits and vegetables are “food” within the meaning of the Food, Drug & Cosmetic Act (FD&C Act), and, as such, subject to adulteration and misbranding provisions of the Act. Agriculture’s regulatory “exemption” from the GMP regulations – which also address sanitation – does not alter the statutory provisions regarding adulteration. FDA could, at any time, take enforcement action against an agricultural producer. FDA has the statutory authority to institute court proceedings to restrain violations of the Act (FD&C Act § 302, 21 U.S.C. § 332), criminally prosecute responsible persons for violations of the Act (FD&C Act § 303, 21 U.S.C. § 333), and seize adulterated or misbranded product (FD&C Act § 304, 21 U.S.C. § 334).

United respectfully submits that as part of the examination of whether and how current GMPs should be revised, FDA should ensure that there is better education about what rules already apply rather than to re-writing regulations or guidance documents to attempt to address issues that are, in fact, already governed under existing authority. Given FDA’s clear regulatory authority over fresh fruits and vegetables and the manufacturing focus of the GMPs, we believe that any revisions to the rule should maintain the GMP exemption for raw agricultural commodities. The produce industry is complex with a diverse supply chain taking fresh fruits and vegetables from production to consumption. The current GMPs are wholly appropriate for food manufacturers, including some segments of the produce industry such as fresh-cut operations. In fact, fresh fruit and vegetable processors/manufacturers have incorporated the GMPs as prerequisites for the establishment of HACCP plans.

But, fresh fruit and vegetable production environments are inherently different from those of manufacturing and as such, should be considered separately. In the mid 1990s, our industry and the FDA evaluated the full range of food safety standards and rules applied throughout the food industry searching for best practices applicable to agricultural production. Public meetings were held to garner input concerning which food safety standards would work best in fresh fruit and vegetable growing, harvesting, packing and storage. The GMP rules were considered at length during this process but ultimately the Agency felt it best to establish a tailored set of guidelines solely for the fresh produce industry. As part of the 1997 Produce and Imported Food Safety Initiative, FDA and the U.S. Department of Agriculture (USDA), in cooperation with the produce industry, developed voluntary guidance on good agricultural practices (GAPs) for the growing and packing of fresh fruits and vegetables.

The produce industry has come to recognize and implement the GAPs under the oversight of the Agency. FDA’s 1998 publication *Guidance to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables* has been instrumental in driving ever increasing attention and commitment to reducing risks throughout our production. Just as food manufacturers have used the GMPs for over a century as the foundation for food safety, so to have fresh fruit and vegetable producers used the agricultural-specific GAPs.

We believe that the Agency’s produce safety efforts must be directed at the continued promotion of the GAPs guidance within the industry—not at revising the GMPs in a manner outside of its current scope. Furthermore, the Agency should remain committed to developing and implementing its action plan “Produce Safety from Farm to Consumption.” These initiatives will make a true difference in the safety of our nation’s fresh produce supply.

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We thank you for the opportunity to submit comments regarding revision to the GMP rules. As the Agency proceeds, we urge you to consider our recommendations. We look forward to continuing to work together with FDA on these important matters and continuing to submit additional comments as the revision process moves forward into rulemaking.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Tom Stenzel". The signature is fluid and cursive, with a large, stylized "S" at the end.

Thomas E. Stenzel
President and CEO
United Fresh Fruit and Vegetable Association

Please Note: These detailed comments provided are supported by A. Duda & Sons, Inc., Potandon Produce L.L.C., Florida Citrus Packers, Georgia Fruit and Vegetable Growers Association, Grower-Shipper Association of Central CA, Texas Citrus Mutual, Texas Vegetable Association, Ventura County Agricultural Association and the Produce Marketing Association.

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